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FOREWORD

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(X) For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 32 CFR 219 and 45 CFR 46.

() In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

Charles M. Loh, PhD
Principal Investigator's Signature

Date

4-30-99

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INTRODUCTION

Background

Despite the decrease in coronary heart disease mortality over the past 30 years, coronary heart disease (CHD) continues to reign as the leading cause of death in men and women. Cardiovascular disease, including CHD, kills nearly 500,000 American women each year and black women generally have a higher prevalence of CHD risk factors and a higher death rate at a younger age than white women (Haan, 1996). Risk factors are highly prevalent in women aged 20-74 years. One third have hypertension, $\frac{1}{4}$ have hypercholesterolemia, $\frac{1}{4}$ are overweight, and $\frac{1}{4}$ are sedentary. These factors are more prevalent in women of lower socioeconomic status and lower educational level (Wenger, 1995). In 1995, an estimated 34.3% of women reported having 1 risk factor and 30% of women reported having two or more of the following risk factors for cardiovascular disease (CVD: hypertension, high blood cholesterol, diabetes, overweight and smoking. The prevalence of two or more risk factors increased with age, decreased with educational level and was higher among black women. The percentage of women with two or more risk factors was significantly higher than estimates from 1992 (Greenlund, et al., 1998).

Consistent with these findings, Poduri & Girsso (1998) found that the mean number of cardiovascular risk factors among low income women was 2.6 and that knowledge and understanding of these risk factors was suboptimal, particularly among women personally affected by risk factors for CVD. Most of these risk factors tend to be higher among ethnic minority women than white women. After adjusting for education there are significant differences in blood pressure, BMI, physical inactivity and diabetes in blacks as compared to whites. After controlling for income and education, African-American women are more than twice as likely as Caucasian women to have report risk factors of obesity and sedentary lifestyle. Moreover, women from lower SES have significantly higher prevalences of smoking and physical inactivity and higher levels of BMI and non-HDL-C than women of higher SES (Winkleby, Kraemer, Ahn, & Varady (1998; Harrell & Gore, 1998). With respect to dietary risk factors, investigator have documented greater consumption of cholesterol and less consumption of potassium in African-American women. Dietary magnesium is also lower in African-Americans. Moreover, magnesium levels are significantly lower in those with prevalent cardiovascular disease, hypertension and diabetes than in those without these diseases (Folsom, et al., 1995; Gates & McDonald, 1997).

Hypertension is one of the single most important risk factors for cardiovascular disease and the prevalence of this disease is greater, appears at an earlier age and is more likely to be associated with end-organ damage in African-Americans (Lackland, & Keil, 1996). Although obesity has been shown to be highly related to cardiovascular risk (Stolley & Fitzgibbon, 1997), the positive association between obesity and blood pressure has been less consistent in African-Americans than whites. Nonetheless, researchers have documented that BMI is positively and independently associated with changes in blood pressure after controlling for weight change and other covariates. Baseline weight and weight gain among those who were initially normal weight were independent predictors of blood pressure increase for African-Americans in the Pitt County Study of

hypertension (Curtis, Strogatz, James & Raghunathan, 1998). Body mass index and African-American race are associated with higher blood pressure with and without drug therapy (Kumanyika et al., 1998). Other research has shown that waist circumference is positively correlated with blood pressure and that waist circumference correlates better with visceral adipose tissue and is a better predictor of cardiovascular disease than are BMI and waist to hip ratio (Okosun et al., 1998). The Coronary Artery Risk Development in Young Adults (CARDIA) study documented a positive association of hypertension with age, body mass index, and alcohol intake and a negative association with physical activity, cigarette use and intake of potassium and protein (Liu et al., 1995).

Although less understood and more difficult to quantify, there have been direct associations between psychosocial stress and blood pressure in African-Americans. Some theoretical models argue that African-Americans are engaged in a chronic struggle to achieve and maintain valued social and personal goals in the context of few socioeconomic resources. This struggle is postulated to be associated with high blood pressure and as contributing to the greater experience of frustration and anger that compounds blood pressure elevation (Dressler, 1996). Emotional support and instrumental support tends to buffer the relationship between stress and blood pressure (Strogatz et al., 1997). Some investigators have shown laboratory analogs of stressful situations have elicited increases in blood pressure (Morris et al., 1996). Work-related stress has been associated with an increased risk of hypertension and more severe cardiovascular problems. In African-Americans high-effort coping plus high job status is associated with high work and laboratory diastolic pressure and higher work systolic pressure (Light et al., 1995). High anxiety and high depression have been shown to be independent predictors of incident hypertension in some **research (Jonas, Franks & Ingram)**. Socioeconomic, educational and lifestyle stressors appear to converge and result in increased sympathetic drive and augmented neurovascular tone. The heightened sympathetic drive as well as the increased vascular reactivity emerge as major contributors to the risk factor cluster in African-American women. Patterns of comorbidity and mortality risk in blacks and whites clearly show that an excess burden of chronic disease in black women as compared to white women (McGee, Cooper, Liao & Durazo-Arvizu (1996). These findings justify targeting women at high risk for cardiovascular disease as one approach for reducing the excess cardiovascular morbidity and mortality among African-American women.

It is well accepted that the standard drug treatment for hypertension often causes adverse side effects that reduce quality of life and is believed to be a causal factor in non-compliance with prescribed anti-hypertensive regimens among blacks and whites (Kaplan, 1990). Despite the fact that anti-hypertensive drug therapy is quite effective in reducing cardiovascular morbidity in blacks, it has been estimated that more than two-thirds of patients are non-compliant with medical regimens. The U.S. Joint National Committee on the Detection, Evaluation and Treatment of High Blood Pressure (JNC, 1997) recommended the use of lifestyle modification therapies as a first line of treatment of mild hypertension and as an adjunctive treatment for stage 2 and 3 hypertension. Although the JNC does not recognize stress reduction therapies as a definitive treatment for hypertension due to the paucity of randomized controlled studies in this area, there is evidence that behavioral interventions such as meditation and progressive muscle

relaxation are effective in lowering blood pressure. A number of studies have shown that meditation is more effective than other stress reduction methods in lowering blood pressure.

In one randomized trial of stress reduction therapies conducted by Schneider and associates (Schneider et al., 1992), the effectiveness of transcendental meditation was compared to progressive muscle relaxation as well as the usual non-drug care (diet and exercise) for managing hypertension in elderly African-Americans. Results indicated that after 3 months of follow-up, TM and PMR showed significant blood pressure reductions compared to the usual care. The significantly greater reductions in the TM group (13/7 mmHg) were of the same order of magnitude as the average blood pressure reductions with drug therapy reported for most clinical trials of mild hypertension (Kaplan, 1990). Whereas this study focused on older African-Americans (age 55 and older) and demonstrated significant reductions in clinic and home blood pressure compared with other groups, there is a need to determine whether meditation will be effective in younger African-Americans and if it will be effective in modifying additional cardiovascular risk factors in this population besides blood pressure.

Reduction of blood pressure in hypertensive patients is an important objective, since pressure-related complications such as stroke, heart failure, and renal insufficiency and failure are significantly reduced or delayed. However, cardiovascular risk factors often cluster which may explain why lowering blood pressure alone does not achieve the expected risk reduction in atherosclerotic events including coronary heart disease. Since meditation appears to reduce the stress and associated increase in sympathetic nervous system activation which contribute to the risk factor cluster, meditation may be effective not only in reducing blood pressure, but other components of the risk factor cluster and angry/hostile responses to stress. The effects of meditation on the risk factor cluster have not been examined in African-Americans. One of the few studies which examined the relationship between meditation on cardiovascular risk factor profile revealed a reduction in blood pressure and other risk factors (smoking, drinking and cholesterol) among long term meditators over a 5 year period (Orme-Johnson, 1987). However, this study was not a randomized clinical trial so causality could not be ascertained. The current research will examine the interrelationships between anger/hostility and both cardiovascular and psychological risk factors for African-American women. Moreover, we will determine if a program of meditation will lower the composite score for risk factor clusters, reactivity to stress and improve family/job stress and work performance more effectively than lifestyle changes alone for African-American women with multiple risk factors for cardiovascular disease.

Specific Aims and Hypotheses for Baseline Measures: Determine the interrelationship between anger/hostility and both cardiovascular and psychological risk factors for African-American women.

Hypothesis 1: Anger/hostility will be positively correlated with blood pressure, lipids, plasma catecholamines and body fat.

Hypothesis 2: Anger/hostility will be positively correlated with negative health practices such as smoking, drinking and sedentary lifestyle.

Hypothesis 3: Anger/hostility will be positively correlated with family and job stress, anxiety and depression.

Hypothesis 4: Anger/hostility will be negatively associated with job performance, productivity at work, relationships with co-workers and supervisors.

Specific Aims and Hypotheses for the Intervention: Determine if transcendental meditation lowers the composite score for risk factor clusters, reactivity to stress and improves reported family/job stress and work performance more effectively than lifestyle change alone for African-American women with multiple risk factors for cardiovascular disease.

Hypothesis 1: Transcendental meditation will reduce the risk factor cluster more effectively than lifestyle changes alone by lowering sympathetic drive and vascular reactivity.

Hypothesis 2: Transcendental meditation will reduce psychological stress (i.e. anxiety, anger, depression), lipids and physiological responses associated with laboratory induced stress and real stress associated as reflected by 24-hour blood pressure and behavioral assessments.

Hypothesis 3: Women who receive training in transcendental meditation will report better relationships with coworkers and supervisors, perform more efficiently and effectively on their jobs and report less stress during the follow-up phase.

Subjects & Design

The risk factor cluster includes overweight/obesity, hypertension, hyperinsulinemia, insulin resistance, dyslipidemia, and anger/hostility. This is a randomized, single blind, controlled study of transcendental meditation versus an intensive lifestyle educational program alone among 150 African-American women ages 18-70 years who have high normal blood pressure to mild hypertension (i.e. blood pressures within the range of 130/85-159/104 will be accepted for inclusion) and at least 2 additional self reported risk factors for cardiovascular disease (i.e. family history of hypertension, overweight, high cholesterol, smoking, drinking, high sodium intake, sedentary lifestyle). All women will have baseline assessments of cardiovascular disease risk factors (hypertension, hyperinsulinemia, overweight/obesity, body fat distribution, dyslipidemia, dietary sodium intake) and psychosocial (anger/hostility, anxiety, depression, family/job stress, stress coping styles, smoking, drinking, sedentary lifestyle) risk factors. These women will be randomly assigned to either the meditation or lifestyle education group. The following women will be excluded from the study: Women greater than 70 years old, taking more than 4 antihypertensive medications, using insulin, having a fasting glucose > 140 mg/dl, manifesting renal insufficiency, evidence of previous myocardial infarction, with history of accelerated or malignant hypertension, diabetes, cerebrovascular accident, unstable angina, congestive heart failure, evidence of major psychiatric illness, alcohol or drug abuse or pregnancy.

Subjects will be recruited from community health screenings and through public advertisement. We plan to obtain the following information from study participants: body fat distribution, fasting lipoprotein profile, blood pressure/hypertension history,

physical activity habits, alcohol consumption, cigarette smoking, job/family stress, job satisfaction, coping styles, life stress information.

The diagnosis of high normal blood pressure to mild hypertension is based upon blood pressure measurements taken during the 3 week baseline clinic measurements. Casual (seated) blood pressure will be obtained in triplicate on the right arm supported at heart level after the participant has rested for five minutes. Phase 5 Korotkoff will define diastolic blood pressure and the two closest blood pressure readings will be average. Only volunteers with blood pressures consistently in the 130/85-159/104 mmHg range over a 3-week period consisting of 3 blood pressure readings will be eligible.

The single blind will be maintained by having research staff who obtain the blood pressure and physiological data remain unaware of the participants intervention status. The two groups will receive equal amounts of professional contact time.

Intervention and Control Group

Each of the active treatments will be introduced in ways that encourage some degree of expectancy and benefits for the prevention of disease and promotion of health. Prior to participation in the interventions, participants will complete a questionnaire about their expectations regarding the treatment and their perceptions of the interventions effectiveness for managing their blood pressure. The transcendental meditation and lifestyle education programs will be taught with similar formats, amount of instructional time, professional attention from the instructor and daily practice time. The general format of instruction in the active treatment will be modeled after the standard meditation training course. This includes an introductory lecture meeting which is done in group format to discuss benefits and mechanisms of the technique, a brief personal interview, a session of personal instruction and follow-up in group meetings. These initial steps will consist of 5 meetings which take place over 4 consecutive days and last about 1 hour per day. At the end of this period, the groups will meet once every other week for roughly 1 1/2 hours for a total of 8 follow-up visits. The meditation technique is a simple mental procedure, practiced twice a day for 20 minutes while sitting with eyes closed. During the technique the ordinary thinking process settles down and a distinctive psychophysiological state of restful alertness appears to be gained.

The lifestyle educational program participants will receive instruction for modifying the major risk factors with conventional behavioral approaches. Participants will receive the same number of sessions as participants in the active intervention condition. Participants will learn about the importance of diet, salt, weight control or management, exercise and the effects of these factors on controlling blood pressure. The group sessions will include information on smoking cessation and promotion of physical activity. The participants will also cover the topic of stress in a didactic format, but no specific instruction in stress reduction or relaxation techniques will be given. Participants in both the meditation and lifestyle education groups will be requested to complete compliance forms to monitor their respective practice/implementation of meditation and lifestyle changes.

Measures

The following is a description of the measures that will be obtained from participants:

Overweight is defined as a body mass index (BMI) 25-27 kg/m² and obesity is defined as BMI 27-40 kg/m² or greater. Defining obesity by BMI does not distinguish between overweight and overfat. Thus, body fat is estimated. **Body fat distribution** will be assessed with skinfolds and waist to hip (WHR). A thicker SS skinfold and a higher SS/TC skinfold ratio have been correlated with cardiovascular risk factors including hypertension and diabetes. The WHRs are associated with insulin resistance, diabetes mellitus (NIDDM), hypertension and coronary heart disease.

Plasma catecholamines and plasma renin activity will be measured through Associated Medical Laboratories.

Dyslipidemias are determined via measurement of a fasting lipoprotein profile including total cholesterol, triglycerides, HDL, LDL, VLDL cholesterol. Hypercholesterolemia is defined according to National Cholesterol Education Program guidelines. Since many hypertensive patients have additional risk factors such as obesity and cigarette smoking, total cholesterol > 200 mg/dl and LDL cholesterol >130 mg/dl are abnormal. Based on evidence from Framingham and other sources, triglycerides >150 mg/dl, particularly in association with HDL-C < 40 for women and <35 mg/dl for men are abnormal. These measure will be determined by Associated Medical Laboratories.

Physical activity, alcohol consumption and cigarette smoking are lifestyle variables which will be assessed with a questionnaire modeled after the **MRFIT** instrument.

Compliance and expectancy will be defined according to methods suggested by Jacobs and Chesney. Participants will record their daily practice of meditation or lifestyle changes on a log sheet for the week. An indirect but objective indicator of compliance is the attendance at the follow up meetings. Attendance records will be kept by the meditation and lifestyle instructors.

Psychosocial Questionnaires will assess a number of dimensions associated with life stress, coping, health behaviors. The following is a description of the primary dimensions assessed & questionnaires:

Health Behaviors: The questionnaire assesses substance use, smoking, drinking, diet, exercise and rest/relaxation. It has been utilized other research trials assessing the impact of meditation on high blood pressure.

SCL-90-R is a multidimensional symptom self-report inventory comprised of 90 items each measured on a 5-point scale of distress from "not at all" to "extremely". The SCL-90 quantifies psychopathology in terms of 9 primary symptom constructs: somatization, obsessive compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. In addition, three global measures reflect distinct aspects of overall psychological distress. Alpha coefficients of reliability range from .77 for the psychoticism dimension to .90 for depression (Derogatis, Rickels & Rock, 1976).

Perceived Stress Home/Work Scales: These items assess the frequency with which individuals feel a sense of control over situations occurring in home and work

environments. The scales are comprised of 14 items each measured on a 5-point frequency scale from "never" to "very often."

Job Satisfaction/Performance: Fourteen items were developed to assess self-reported job satisfaction, indicators of performance (i.e. past job reviews, absences, sick leave, etc.) and relationships with co-workers.

Social Support: Items from the National Survey of Black Adults were utilized to assess tangible and intangible social support.

The Rationality/Emotional Defensiveness Scale & Interpersonal Behavior Scales: This scale consist of 12 statements that describe rational, non-emotional reactions in interpersonal relationships and the need to maintain harmony in relationships (Spielberger, 1987). Items measure how often individuals react to prescribed situations by having them rate themselves on a 4-point frequency scale from "almost never" to "almost always". Alpha reliabilities for these scales range from .72 in cancer patients to .70 in non-patient samples. This scale was based upon findings from Grossarth-Maticcek et al. (1985) who reported that the incidence and mortality of both cancer and ischemic heart disease were higher in those who repress or deny their emotions.

The State-Trait Anxiety Inventory : This scale consists of 44 items which form five primary scales and two subscales. It provides a brief objectively scored measure of the experience, expression and control of anger (Spielberger, 1988). This scale measures the intensity of anger as an emotional state (state anger) and the disposition to experience angry feelings as a personality trait (trait anger). Frequency of anger expression is assessed by 3 subscales: anger-out, anger-in and anger-control.

The Cope: The cope is a multidimensional coping inventory which assess the different ways in which people respond to stress. Subscales measure distinct aspects of problem focused coping (seeking emotional support, positive reinterpretation, acceptance, denial, turning to religion) and coping in less useful non-problem focused ways (i.e. venting, behavioral disengagement, mental disengagement) (Carver, Scheier & Weintraub, 1989).

BODY

Experimental Methods/Procedure

One hundred fifty African-American women participants will undergo three phases of the research. The first phase is a 3-week baseline assessment of blood pressure to determine eligibility, medical history and cardiovascular reactivity stress test and blood draw. Casual (seated) blood pressure will be obtained in triplicate on the right arm supported at heart level after the participant has rested for five minutes. Phase 5 Korotkoff will define diastolic blood pressure and the two closest systolic blood pressure readings will be average. Only volunteers with blood pressures consistently in the 130/85-159/104 mmHg range over a 3-week period consisting of 3 blood pressure readings will be eligible. At their 2nd blood pressure assessment, patients will complete a medical interview questionnaire packet which assesses health behaviors, coping, anger/hostility, etc. At their 3rd visit to the clinic, following their 3rd blood pressure assessment, participants will undergo a cardiovascular reactivity test. The tests used

represent a range of autonomic stressors from relatively selective beta-adrenergic stressors (mental arithmetic) to relatively selective alpha-adrenergic stressors (forehead cold pressor). Participants systemic hemodynamic (blood pressure, heart rate) response will be obtained at 2 minute intervals in those tests or recovery periods lasting more than 4 minutes. The following depicts the tasks utilized in the reactivity protocol.

- a. Resting baseline (sit quietly for 5 minutes then start 10 minute baseline)
- b. Arithmetic test (6 minutes)
- c. Rest and recovery (3 minutes)
- d. Fore head cold pressor test (90 seconds)
- e. Rest and recovery (3 minutes)
- f. Stress interview (10 minutes)
- g. Rest and recovery (20 minutes)

In addition to the reactivity protocol, all patients will have their weight measured and a body fat distribution assessment conducted using skin fold calipers for biceps, triceps, suprailiac, and subscapular. Waist, and hip measurements will also be taken to determine the waist to hip ratio for patients. Patients will undergo ambulatory blood pressure monitoring following the reactivity protocol. They will be connected to an ambulatory blood pressure monitor which will record blood pressure and heart rate over a 24-hour period. Finally, patients will undergo a blood draw so that blood chemistry profiles can be measured. This completes phase one of the project. During phase two, patients will be randomly assigned to either receive lifestyle modification or transcendental meditation. Within a month of assignment patients will begin their intervention groups which will involve 13 visits to the clinic for 1 ½ hour sessions. These visit will occur consecutively for the health education group and will occur bimonthly for the TM group after the first 5 consecutive steps in the TM training. Despite the slight variation in format, both groups will receive the same amount of time and attention from interventionists and will occur relatively within the same time frame. Following the completion of the intervention all participants will complete a follow-up assessment which involves completing an post-test medical history questionnaire and a follow-up cardiovascular reactivity test and blood draw. This completes phase two of the project. Phase three of the project involves patients returning for a six-month follow-up medical history questionnaire, blood draw and reactivity test.

Project Status

During period from the inception of the study in 1995-1996, Ernest H. Johnson, Ph.D. was the principal investigator for the contract. After his resignation in 1996 the project was temporarily suspended. At this time there was no available data to indicate progress on the contract. In September, 1997, Charlie M. Lollis, Ph.D. formally assumed the role of principal investigator and resumed the project. During 1997-1998, administrative and start-up procedures were executed. A two-year no-cost extension was requested and granted so as to complete the specific objectives of the project. In September, 1998 recruitment of participants for the program ensued. Because of

difficulties recruiting the targeted group due to stringent selection criteria and difficulties recruiting and maintaining African-American patients into clinical trials, there are few women enrolled into the protocol. However, we expect to enroll significantly more participants in ensuing months with more aggressive modes of recruitment (i.e. more large-scale community screenings, more aggressive contacts with physicians for referrals, advertisement, etc.).

To date, there are a total of 20 women who are enrolled in the study (10% of the projected sample. Eighteen of these women have been randomized (8 to TM, 10 to lifestyle modification). Currently, we have 9 additional women who are in the screening phase of the baseline assessment all of which have pre-qualifying blood pressures which make them eligible for continued participation at this time. With successful enrollment of these individuals we will have recruited 19% of our sample. Our timeline for completion of recruitment is December, 1999. We anticipate enrolling a minimum of 17 women per month from May, 1999 through December which will achieve our recruitment goal of 150 women. This can be achieved with aggressive recruitment techniques.

Following completion of the intervention, data collected from baseline assessment will be organized to examine the interrelationship between psychosocial factors and cardiovascular risk factors. The hypotheses for the baseline measures will be addressed using correlational, multiple regression analyses and analysis of covariance. An alternative way of approaching these hypotheses is to form high vs low anger/hostility classifications from the examination of the distribution of scores on the Trait-Anger subscale and the Cook-Medley Hostility Questionnaires. There are normative data for these measures and high scores can be designated as those at or above the 75th percentile. Therefore, high vs low anger/hostility groups can be defined to determine the extent that anger/hostility is related to cardiovascular risk factors and psychosocial factors as specified in the specific aims.

To analyze the effectiveness of the interventions will use analysis of covariance statistics. To determine the effectiveness of the interventions across time we will use repeated analysis ANOVA. Dependent variables will consist of the risk factor cluster scores that will be computed by assigning a score of one for each of the risk factors: high-normal blood pressure, hyperinsulinemia, overweight, dyslipidemia and high anger/hostility. Other risk factors (e.g. smoking, drinking, etc.) will be used as covariates. Reduction of cardiovascular responses to laboratory stress will be evaluated using multiple ANOVA with the covariates being the baseline measures preceding the lab stressors. The within group factors will be pre-/post –treatment levels while the between group factors will be the two treatment conditions. The reactivity data could also be analyzed using the resting baseline periods to calculate delta change scores and submitting these to the appropriate analyses. The effectiveness of the interventions in reducing blood pressure response to natural stress will be determined from the assessment of 24-hour blood pressure readings. Treatment group effects can be analyzed using ANOVA and ANCOVA techniques. The changes on the battery of psychosocial measures will be assessed using repeated measures ANCOVA. Longitudinal data (6-month follow-up data) will be analyzed using regression techniques.

CONCLUSIONS

Until further data is collected, results are inconclusive at this time. Nonetheless, we expect our findings to have significant implications for complementary medicine practices with respect to the treatment of hypertension and other cardiovascular disease risk factors via non-pharmacological stress reduction therapies.

QUARTERLY PROGRESS REPORT
Period Ending November 30, 1998

1. Contract Number: DAMD 17-95-C-5067
2. Report Date: 11/30/98
3. Reporting Period: December 1, 1998-February 28, 1999
4. PI: Charlie M. Lollis, Ph.D.
5. Telephone Number: (404) 756-5753
6. Institution: Morehouse School of Medicine
7. Project Title: Managing Multiple Risk Factors for Cardiovascular Disease through Anger/Hostility Control and Meditation
8. Current staff with percent effort of each on project:

Charlie M. Lollis, Ph.D. (P.I.)	50%
Teresa Stewart	50%
Karen Parker	50%
Quincy Preston	50%
9. Contract Expenditures: See Attached List of Expenditures
10. Comments on administrative and logistical matters:

Organizational structure for the office continued to be modified to establish most efficient means of conducting the project with respect to staff's daily responsibilities. Research coordinator submitted letter of resignation to pursue other personal goals. Recruitment for a new project manager ensued. Goal is to recruit a Ph.D. level project administrator. A graduate assistant was hired for 12 hours a week as a consultant to assist in project delivery and recruitment. Goal is to hire additional staff to assist in recruitment and to assist in conducting cardiovascular reactivity laboratories and medical interviews so that we can open our clinic during evening hours. This may assist in recruitment. Also, goal is to hire telemarketers to follow up with patients from blood pressure screening so as to increase the number of individuals scheduled for initial screenings. Blood pressure screenings and call night schedules temporarily hindered by the loss of a key staff member, however recruitment continues to progress. Recruitment difficulties may partially stem from stringent selection criteria (i.e. no comorbid conditions with high normal blood pressure are accepted in the protocol) as well as the difficulties found in other research protocols with enrolling minority populations in clinical trials. Opportunities to do radio advertisement being explored. Interventions for cycle 1 of participants ensued mid-February.

11. Use additional pages, as necessary, to describe scientific progress in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible.

Out of 9 participants randomized to cycle 1, 6 received instruction in either health education or meditation. The other 3 participants will be recycled when the next phase of groups begin in April.

QUARTERLY PROGRESS REPORT

Period Ending February 28, 1999

12. Use additional page(s) to present a brief statement of plans or milestones for remaining of current period:

The major milestone for the remaining of current budget period is to recruit and enroll 141 women into the project. This goal will require that we enroll a minimum of 20 women on a monthly basis between February, 1999 and August, 1999. Our means for accomplishing our goals is to schedule more blood pressure screenings and hire additional staff to assist with scheduling patients for follow-up screenings in our clinic. Our goal is to begin an intervention group every 4 weeks between February, 1999 and August, 1999.

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